

Message

From: Robbins, Chris [Robbins.Chris@epa.gov]
Sent: 3/1/2021 4:01:12 PM
To: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]; Matthews, Lisa [Matthews.Lisa@epa.gov]
Subject: RE: Please advise FW: 1,4-Dioxane

Yes – Lisa and I are meeting this afternoon and this is on the agenda...thx

Christopher S. Robbins
Deputy Assistant Administrator for Management
Office of Research and Development
(919) 541-0605
Mobile: Ex. 6 Personal Privacy (PP)

From: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Sent: Monday, March 1, 2021 10:59 AM
To: Robbins, Chris <Robbins.Chris@epa.gov>; Matthews, Lisa <Matthews.Lisa@epa.gov>
Subject: RE: Please advise FW: 1,4-Dioxane

So will this be added to the backgrounder for me for the ecos mtg?

Jennifer Orme-Zavaleta, PhD
Acting Assistant Administrator, and
Principal Deputy Assistant Administrator
Office of Research and Development
US Environmental Protection Agency

DC
Cell: Ex. 6 Personal Privacy (PP)

From: Robbins, Chris <Robbins.Chris@epa.gov>
Sent: Monday, March 1, 2021 9:51 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Subject: FW: Please advise FW: 1,4-Dioxane

Here's another thing that came up late last week...

Christopher S. Robbins
Deputy Assistant Administrator for Management
Office of Research and Development
(919) 541-0605
Mobile: Ex. 6 Personal Privacy (PP) 1

From: Rodan, Bruce <rodan.bruce@epa.gov>
Sent: Saturday, February 27, 2021 11:09 AM
To: D'Amico, Louis <DAmico.Louis@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>
Cc: Robbins, Chris <Robbins.Chris@epa.gov>; Matthews, Lisa <Matthews.Lisa@epa.gov>; Trentacoste, Emily <trentacoste.emily@epa.gov>
Subject: FW: Please advise FW: 1,4-Dioxane

Lou,

Cc'ing you on an email from yesterday. Thanks for the review of the "appendix." Similar questions ... but maybe some additional core considerations ...

Dr. Bruce Rodan
Associate Director for Science
EPA Office of Research and Development

From: Rodan, Bruce
Sent: Friday, February 26, 2021 5:48 PM
To: Matthews, Lisa <Matthews.Lisa@epa.gov>
Cc: Robbins, Chris <Robbins.Chris@epa.gov>
Subject: RE: Please advise FW: 1,4-Dioxane

Lisa,

Ex. 5 Deliberative Process (DP)

Lisa – happy to chat.

Dr. Bruce Rodan
Associate Director for Science
EPA Office of Research and Development

From: Matthews, Lisa <Matthews.Lisa@epa.gov>
Sent: Friday, February 26, 2021 11:14 AM
To: Rodan, Bruce <rodan.bruce@epa.gov>
Subject: Please advise FW: 1,4-Dioxane

Hi Bruce, is or
Chris asked me to send this to you to get your take.

This was circulated for agency review last summer – including SHC, HERA, OSAPE, RSLs and STLs. Only OLEM and OW provided comments (attached).

Thanks,
Lisa

From: Matthews, Lisa
Sent: Friday, February 26, 2021 10:22 AM
To: Robbins, Chris <Robbins.Chris@epa.gov>
Subject: FW: 1,4-Dioxane

I need some advice on this one. This appears to be less about the ITRC 1,4-Dioxane Report specifically, and more about EPA's approaches to cancer risk assessment.

This is an unfortunate consequence of no one in ORD taking the time to review and provide comment on the draft ITRC document that came out last summer.

From: Patricia Reyes <preyes@ecos.org>
Sent: Friday, February 26, 2021 10:07 AM
To: Matthews, Lisa <Matthews.Lisa@epa.gov>
Subject: Re: 1,4-Dioxane

Hi Lisa,
I talked to Randy Chapman and other Board members and they feel that we should follow our process completely - which is what we did. EPA had 5 EPA folks make 39 comments on the external review and the majority of comments were on the TOX section, and all were incorporated. There were also 5 people from NJDEP on the team and their comments were incorporated. The team leaders are completely opposed to removing or hiding the document on the web until this is resolved with specific comments from new experts. This is also not how we normally update a document but if the document is wrong of course we will make a change. So please send the EPA comments whenever you can and we will let NJDEP also know that EPA is taking another look at it.

Thanks,

Patricia Catherwood Reyes
Director, Interstate Technology Regulatory Council
1250 H STREET NW SUITE 850
Washington, D.C. 20005
202-266-4933, (c) 202-590-4621

"Do the best you can until you know better; then when you know better, do better."

On Thu, Feb 25, 2021 at 3:06 PM Matthews, Lisa <Matthews.Lisa@epa.gov> wrote:

Please delete the text until further more comprehensive review can be done by the appropriate people in EPA.

From: Matthews, Lisa
Sent: Thursday, February 25, 2021 3:03 PM
To: 'Patricia Reyes' <preyes@ecos.org>
Subject: RE: 1,4-Dioxane

Gloria Post was right in highlighting this issue. It seems like EPA could note problem areas to ITRC. I'll try to get a sense of how long that will take.

I've asked for a quick response on this specific issue.

From: Patricia Reyes <preyes@ecos.org>
Sent: Thursday, February 25, 2021 1:56 PM
To: Matthews, Lisa <Matthews.Lisa@epa.gov>
Subject: 1,4-Dioxane

Hi Lisa,

Sorry to bother you but I received a few calls from NJDEP this week regarding our 1,4Dioxane report that we finalized last month and its published on their website. Apparently, their top toxicologist, Gloria Post just read the document including Appendix C on Toxicology and she is very upset to say the least. She sent an email asking who at USEPA reviewed the document and how EPA could have let the report out with the language below. I am looking for the EPA comments now but I think the only ones we received were from OLEM and they were very high level, no details and nothing on toxicology - and I'm not sure the reviewer was working on 1,4-DX. For instance, below is a statement from NJDEPs email requesting EPA review today. Is there someone you can send the document link to and ask them to provide comments or agree or disagree with NJDEP so we know we have it all correct?? Please let me know and how much time you will need to get a response. Thanks!

The link to the full final document is: <https://14d-1.itrcweb.org/>

Language below provided by NJDEP:

from the Introduction at the beginning of Appendix C. It casts doubt on the EPA approach for cancer risk assessment (which is also used by all) states, in general, not just specifically regarding 1,4-dioxane.

"It is important to recognize that significant controversy and argument exists over USEPA's use of threshold approaches to cancer risk assessment, especially when a chemical is not acting through a mutagenic MOA, such as 1,4-dioxane. **Historically, scientific fraud and misconduct have been identified in how radiation-induced cancer risks were designated to be a linear, dose-proportional concept (Calabrese 2019).** USEPA adopted the Linear No Threshold approach (LNT) emerging from the Biological Effects of Ionizing Radiation's (BIER I) genetics panel for addressing chemically induced cancer risk. Since USEPA adopted BIER I's LNT model in the mid-1970s, significant research and analysis on chemical carcinogenesis has been published supporting the use of thresholds as the basis for many types of chemically induced cancers (Lutz et al. 2002; Wolf et al. 2019; Doe et al. 2019; Tubiana et al. 2009; Bogen 2016; Bevan and Harrison 2017; Felter et al. 2018)."

"Here, it is stated as a fact that the basis for the EPA cancer risk assessment approach (radiation-induced cancer risk) has been identified as being associated with fraud and misconduct, citing Calabrese (2019). Calabrese's conclusions about this topic are not generally accepted by the scientific community. "

"Because of this and other potentially problematic statements about EPA cancer risk assessment approaches, I request that someone in a position of authority at EPA who is involved with ITRC (not necessarily a member of the 1,4-Dioxane Team) also review the information about EPA cancer risk assessment included in the 1,4-Dioxane document."

Patricia Catherwood Reyes
Director, Interstate Technology Regulatory Council
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